

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS INC.,)
)
)
Plaintiff,)
)
)
v.) C.A. No. 15-919-CFC
)
)
WEST-WARD PHARMACEUTICALS)
INTERNATIONAL LIMITED &)
WEST-WARD PHARMACEUTICALS)
CORP.,)
)
Defendants.)

**CONSENT JUDGMENT AND PERMANENT INJUNCTION
AS TO WEST-WARD PHARMACEUTICALS INTERNATIONAL
LIMITED & WEST-WARD PHARMACEUTICALS CORP.**

This matter is before the Court on the unopposed motion of Plaintiff Vanda Pharmaceuticals Inc. (“Vanda”) and Defendants West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp., which are now known respectively as Hikma Pharmaceuticals International Limited and Hikma Pharmaceuticals USA Inc. (collectively, “Hikma”).

WHEREAS, Vanda owns United States Patent No. 9,138,432 (“the ‘432 patent”).

WHEREAS, Hikma submitted Abbreviated New Drug Application No. 205480 (“Hikma’s ANDA”) to the FDA under 21 U.S.C. § 355(j) seeking to obtain approval to commercially manufacture and sell generic iloperidone.

WHEREAS, in this Action, Vanda alleges that Hikma infringed claim 1 of the '432 patent under 35 U.S.C. § 271(e)(2) by virtue of Hikma's submission of Hikma's ANDA to the FDA.

WHEREAS, in this Action, Vanda alleges that it would be irreparably harmed if Hikma were not enjoined from infringing or actively inducing or contributing to infringement of claim 1 of the '432 patent.

WHEREAS, in this Action, Vanda requested that this Court enter a permanent injunction enjoining Hikma from infringing the '432 patent.

WHEREAS, in this Action, Hikma has denied that the '432 patent is valid, enforceable, and infringed by the product described in Hikma's ANDA.

WHEREAS, Vanda and Hikma have reached an agreement to finally settle the Litigation as set forth in this Consent Judgment and Permanent Injunction as to Hikma and a separate License Agreement ("License Agreement") which is contemporaneously and separately being executed.

WHEREAS, final settlement of this Action will help Vanda and Hikma avoid the substantial uncertainty and risks involved with prolonged litigation.

WHEREAS, final settlement of this Action will permit Vanda and Hikma to save litigation costs, as well as adhere to the judicially recognized mandate that encourages the settlement of litigation whenever possible.

WHEREAS, final settlement of the Action serves the public interest by saving judicial resources and avoiding the risks to each of Vanda and Hikma associated with infringement.

WHEREAS, Vanda and Hikma each consent to personal jurisdiction in Delaware for purposes of enforcing the License Agreement.

IT IS HEREBY ORDERED, DECREED, and ADJUDGED as follows:

1. The Court has jurisdiction over Vanda and Hikma and the subject matter of this Litigation.

2. Hikma acknowledges Vanda's ownership and standing to sue for infringement of the '432 patent.

3. Hikma acknowledges that '432 patent is valid and enforceable, as described more fully and subject to the restrictions contained in the License Agreement.

4. Hikma acknowledges that it has technically infringed the '432 patent under 35 U.S.C. § 271(e)(2) and that Vanda did not authorize the commercial manufacture, use, sale, offer for sale, importation and distribution of the product described in Hikma's ANDA.

5. Hikma and its affiliates are permanently enjoined as of the date hereof from infringing the '432 patent by the commercial manufacture, use, offer to

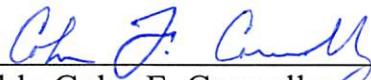
sell, sale, importation, or distribution of any generic iloperidone products that are the subject of Hikma's ANDA that is not pursuant to a license granted by Vanda or otherwise exempt from infringement under 35 U.S.C. § 271(e)(1), and from inducing others to infringe or contributing to the infringement of the '432 patent by inducing others to manufacture, use, offer to sell, sale, import, or distribute or contributing to others' manufacture, use, offer for sale, sale, importation, or distribution of any generic iloperidone products that are the subject of Hikma's ANDA that is not pursuant to a license granted by Vanda or otherwise exempt under 35 U.S.C. § 271(e)(1).

6. All claims and counterclaims in this Action are hereby dismissed without prejudice.

7. Each party shall bear its own costs and attorneys' fees.

8. This Court shall retain jurisdiction over Hikma and Vanda for the purpose of enforcing the terms of this Consent Judgment and Permanent Injunction and over any matters related to or arising from the interpretation or enforcement of the License Agreement or any legal or equitable claim concerning the License Agreement by any third party.

IT IS SO ORDERED, DECREED AND ADJUDGED this 13th day of
September, 2022 by:



The Honorable Colm F. Connolly
United States District Judge

Agreed to:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP POTTER ANDERSON & CORROON LLP

/s/ *Derek J. Fahnestock*

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Dated: September 13, 2022

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